

Perioperative ischemic evaluation study (POISE study)

Submission date 19/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/08/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/02/2009	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.phri.ca/poise.htm>

Contact information

Type(s)

Scientific

Contact name

Dr Philip Devereaux

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00182039

Secondary identifying numbers

MCT-50851, ACTRN012605000308695

Study information

Scientific Title**Acronym**

POISE

Study objectives

Perioperative metoprolol will reduce the 30 day risk of major cardiovascular events in patients undergoing noncardiac surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

McMaster University Research Ethics Board approved on 25th April 2002

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet**Health condition(s) or problem(s) studied**

Cardiovascular

Interventions

Patients will be randomly assigned to either the experimental intervention of oral metoprolol or the control intervention, a placebo. Patients will receive their first dose of metoprolol CR or placebo two to four hours pre-operatively at a strength of 100 mg (1/2 of a 200 mg tablet). Patients will then receive their second dose of their assigned intervention during the first 6 hours or at 6 hours post surgery. Twelve hours after the second post-op dose, patients will start taking a daily dose of 200 mg of either metoprolol CR or placebo for a duration of 30 days post surgery.

For further information, please contact Dr Devereaux at the address listed below or Dr Homer Yang at Ottawa Hospital (hyang@ottawahospital.on.ca).

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Metoprolol

Primary outcome measure

Cardiac death at 30 days, nonfatal myocardial infarction (MI), and nonfatal cardiac arrest

Secondary outcome measures

1. Length of hospital stay
2. Length of stay in an ICU/CCU
3. Revascularisation procedures (i.e. coronary artery bypass surgery and percutaneous transluminal coronary angioplasty)
4. Pulmonary oedema
5. Clinically significant atrial fibrillation
6. Stroke
7. Total mortality
8. Rehospitalisation for cardiac reasons
9. Myocardial infarction
10. Nonfatal cardiac arrest
11. Cardiovascular mortality
12. Clinically significant hypotension
13. Clinically significant bradycardia

Overall study start date

01/09/2002

Completion date

01/04/2007

Eligibility**Key inclusion criteria**

1. Greater than or equal to 45 years of age, either sex
2. Have an expected length of stay greater than or equal to 24 hours
3. Fulfill any one of the following six criteria:
 - 3.1. Coronary artery disease
 - 3.2. Peripheral vascular disease
 - 3.3. History of stroke due to atherothrombotic disease
 - 3.4. Hospitalisation for congestive heart failure within 3 years of randomisation
 - 3.5. Undergoing major vascular surgery
 - 3.6. Any three of the following seven criteria: scheduled for high risk surgery (i.e. intraperitoneal or intrathoracic), emergency/urgent surgery, any history of congestive heart failure, history of a

transient ischaemic attack (TIA), diabetes and currently on an oral hypoglycaemic agent or insulin therapy, preoperative serum creatinine greater than 175 µmol/l (greater than 2.0 mg/dl), or age greater than 70 years
4. Are able to give written consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

10,000

Key exclusion criteria

1. Contradiction to metoprolol including any of the following: significant bradycardia (heart rate less than 50 beats per minute); second or third degree heart block without a pacemaker, asthma that has been active within the last decade, and history of chronic obstructive pulmonary disease (COPD) with bronchospasm on pulmonary function tests
2. Clinical plan to use a beta-blocker preoperatively or during the first 30 postoperative days prior adverse reaction to a beta-blocker
3. Coronary artery bypass graft (CABG) surgery with complete revascularisation in the preceding 5 years and no evidence of cardiac ischaemia since the CABG surgery
4. Patients undergoing low risk surgical procedures (potential examples include transurethral procedures [transurethral prostatectomies {TURPs}, stone baskets etc.], ophthalmologic procedures under topical or regional anaesthesia [cornea transplants, cataract surgery etc.], and surgeries with limited physiological stresses [digital re-implantation, nerve repairs etc.])
5. Concurrent use of verapamil
6. Prior enrolment in this trial

Date of first enrolment

01/09/2002

Date of final enrolment

01/04/2007

Locations**Countries of recruitment**

Australia

Canada

Study participating centre

Clinical Epidemiology & Biostatistics
Hamilton, Ontario

Canada
L8N 3Z5

Sponsor information

Organisation

McMaster University (Canada)

Sponsor details

1200 Main Street West
Hamilton, Ontario
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+1 905 521 2100 ext 22465
townsend@mcmaster.ca

Sponsor type

University/education

Website

<http://www.mcmaster.ca/>

ROR

<https://ror.org/02fa3aq29>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-50851)

Funder Name

National Health and Medical Research Council (NHMRC) (Australia)

Alternative Name(s)

NHMRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Australia

Funder Name

Australia Clinical Trials Grant (Australia)

Funder Name

British Heart Foundation (UK)

Alternative Name(s)

the_bhf, The British Heart Foundation, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

Astra Zeneca (International)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Results article](#)

results

31/05/2008

Yes

No